XpanDH

Expanding Digital Health through a pan-European EHRxF-based Ecosystem

D3.3 – (D3.2.1) Intermediate readiness model evaluation process

WP3 – Organisational readiness

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What did this document aim to achieve?	[In NO MORE than 5-7 lines]
Present the main methodological approaches in bullet point format	
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	
Which project stakeholder group would benefit the most from the document and why?	

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List of abbreviations

Acronym	Description
Antilope	Adopting New Technologies in the Lifecycle of Electronic Health Records
CASforEU	Conformity Assessment Scheme for Europe
Digital Transformation of Health and Care	A part of Digital Single Market empowering citizens and building a healthier society
EEHRxF	European electronic health record exchange format
EHDS	European health data space
eHDSI	eHealth digital service infrastructure
eHDSI Member State Expert Group (eHMSEG)	Composed of Technical, Semantic or Organisation Experts according to the configuration, nominated by the participating Member States. It performs the operational impact assessment
eHealth	The World Health Organisation defines eHealth as the use of information and communication technologies (ICT) for health
eHealth Digital Service Infrastructure (eHDSI)	The term used for the generic and core services for the cross-border health data exchange under the Connecting Europe Facility financing
Electronic Health Record (EHR)	A collection of longitudinal medical records or similar documentation of an individual in digital form. This set of health information based on the principle one EHR per patient in a country
Electronic Health Record Exchange Format (EHRxF)	Seeks to facilitate the cross-border interoperability of EHR, currently being developed by EC, the recommendation released in 2019
ePrescription (eP)	A system allowing to prescribe and dispense medicinal products. It is generally understood as a prescriber's ability to electronically create an accurate, much less error-prone and understandable prescription. The electronic prescription may be either directly sent to a pharmacy or to an ePrescription vault from where every pharmacy can retrieve it. ePrescription may be also used by nurses to administer medicines and by pharmacies to review orders and manage the supply of medicines
epSOS	European Patients Smart Open Services
Euro-CAS	European Clinical Application Suite
FHIR	The HL7 FHIR (Fast Healthcare Interoperability Resources) standard defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems. It allows healthcare information, including clinical and administrative data, to be available securely to those who have a need to access it, and to those who have the right to do so for the benefit of a patient receiving care. The standard is developed by HL7 (Health Level Seven) using a collaborative approach.
GDPR	REGULATION (EU) 2016/67 general data protection regulation
Health Care Provider (HCP)	An individual healthcare professional or a healthcare institution licensed to provide medical care

Health Level 7 (HL7)	HL7 is a standards development organization, publishing a set of standards for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems.
HIMSS	Healthcare Information and Management Systems Society
HIT	health information technology
International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD)	The purpose of the ICD is to permit systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or areas and at different times. The ICD is used to translate diagnosis of diseases and other health problems from words into an alphanumeric code, which permits easy storage, retrieval and analysis of the data
Interoperability	The ability of different systems, organizations or countries to exchange (health) information and use it meaningfully. That means the participants must be able to understand and interpret the shared information correctly, which basically means using the same standards and processes to provide an eHealth service
Logical Observation Identifiers Names and Codes (LOINC)	A terminology for laboratory and clinical observations to send clinical data electronically
NIS / NIS2	Network and information systems / The "NIS 2 Directive," or simply "NIS2," is a European Union directive that specifies cybersecurity requirements that need to be implemented by EU companies that are considered to be critical infrastructure.
Patient Summary	A standardized set of basic medical data that includes the most important clinical facts required to ensure safe provision of healthcare. This summarized version of the patient's medical data gives health professionals the essential information they need to provide care in the case of an unexpected or unscheduled medical situation (e.g. emergency or accident)
Refined eHealth European Interoperability Framework (ReEIF)	Provides a common framework of terms and methodologies that serves as a key instrument to address eHealth interoperability issues
X-Bundle	The so-called X-bundles, an aggregation of interoperability assets that support the connection of health systems in different ways, based on EEHRxF specifications.
Zero Trust	Zero Trust is a security model based on the principle of maintaining strict access controls and not trusting anyone by default, even those already inside the network perimeter.

Executive summary

In the introduction chapter we define the scope of the deliverable, outlining what objectives will be achieved. We also detail the methodology, describing the approach and techniques used to analyse and present the information. Additionally, we identify the key aspects to be analysed, such as technical readiness, interoperability and security. Finally, we discuss the factors to be considered when approaching the models, including regulatory requirements, stakeholder needs and existing technological infrastructure.

In Chapter 2 we provide a summary of several maturity models. These models outline the steps necessary for stakeholders to achieve an adaptable and interoperable technological level while meeting specified security standards. Furthermore, we address the challenges and solutions related to connecting countries where decentralized or mixed systems operate instead of centralized ones. This includes strategies for ensuring seamless integration and cooperation among diverse technological environments.

In Chapter 3, we propose a methodology to generalize the solution developed as a result of the project. This involves transforming the business case to promote widespread adoption and scalability. We suggest moving from digital handshake approach to a "circle of trust" model, which enhances trust and security among the actors. This shift aims to create a more solid and reliable framework for data exchange.

In Chapter 4, we provide suggestions based on deliverable D3.1. We define the X-Bundle Readiness model, which provides a structured framework for assessing and improving the readiness of institutions. This model includes criteria for evaluating technological capabilities, interoperability, security, and compliance, hence providing guidance for stakeholders to enhance their level of readiness.

In Chapter 5, we examine the compliance assessment across different Bubbles, noting significant differences. These Bubbles represent distinct clusters/groups, each with unique characteristics and compliance requirements. This chapter, therefore, is constructed as a study of those differences between these groups with regard to compliance standards, the reasons behind these differences, and their implications for overall system integration and interoperability.

1 Introduction

The level of maturity is particularly critical, as the level and type of guidance depends on the level of readiness of each organization, both from a technical and organizational point of view. When determining the level, the regulatory and operational characteristics of the member countries must be taken into account, and the peculiarities of connecting countries with decentralized or mixed health systems should be addressed. How will the data be exchanged, what is the connection to the common protocol, what are the income and outcome points.

Furthermore, it shall be assessed whether health care providers are at an adaptable and interoperable technological level and meet the specified security level.

Sharing of medical data among different organizations, regions and countries can only succeed, if the stakeholders can be convinced that consistency is ensured in the system, and they can get a guarantee for their data protection.

2 Maturity models

From the point of view of the stakeholders, the principle of reciprocity should be fulfilled. Health care reciprocity has been gaining momentum globally, and it can be defined as the mutual recognition of healthcare qualifications, licenses, and/or certifications among different jurisdictions. Stakeholder groups need to be convinced (digital handshake) in order for data exchange to work based on trust levels. The health system of one member country must trust the health system of another member country and vice versa, and this is also true for the process within the country, so for the relationships between the X-bubbles, which is the basis of the x-bundle if can implement it. The recommended common methodological approach to this is that each system, each connected X-bubble element, has to be assessed to determine the maturity level.

The development of X-bundles will establish common ground for eHealth interoperability by using common international standards and formed connections to ensure that the exchange of health data takes place smoothly. It will benefit all European citizens who use MyHealth@EU services, which currently features ePrescription/eDispensation, Patient Summaries and, in the near future, laboratory reports, medical images and hospital discharge letters, as stated in EEHRxF specifications.

2.1 HIMSS maturity models

HIMSS (Healthcare Information and Management Systems Society) maturity models are frameworks used to assess and guide the maturity level of healthcare organizations in their adoption and implementation of health information technology

(HIT) and electronic health records (EHRs). HIMSS has developed several maturity models tailored to different aspects of healthcare IT.

The HIMSS maturity models typically consist of a series of stages or levels through which healthcare organizations progress as they enhance their IT capabilities and infrastructure. These models provide a structured approach for organizations to evaluate their current state, set goals for improvement, and track their progress over time.

Some of the key HIMSS maturity models include:

- EMR Adoption Model (EMRAM): This model focuses on electronic medical record (EMR) adoption and assesses an organization's capabilities across eight stages, from completely paper-based processes to fully integrated electronic systems.
- Analytics Maturity Model (AMAM): The Analytics Maturity Model helps healthcare organizations assess their capabilities in utilizing data analytics to improve decision-making, clinical outcomes, and operational efficiency.
- Continuity of Care Maturity Model (CCMM): This model focuses on the seamless exchange of patient information across care settings to support coordinated and patient-centered care delivery.
- Infrastructure Adoption Model (INFRAM): The INFRAM evaluates an organization's infrastructure capabilities, including its networking, security, and data center operations, to support the delivery of healthcare services.
- Clinical & Business Intelligence Maturity Model (C&BI MM): This model assesses an organization's maturity in leveraging clinical and business intelligence tools to derive insights from data for strategic decision-making and performance improvement.
- Population Health Management (PHM) Maturity Model: This model focuses on assessing an organization's capabilities in managing the health of populations, including risk stratification, care coordination, and patient engagement.

These maturity models serve as valuable tools for healthcare organizations to benchmark their progress, identify areas for improvement, and prioritize investments in IT infrastructure and capabilities to better support patient care delivery and organizational goals.

2.2 Artefacts from maturity level of Hospital on FHIR, Antilope and Euro-CAS

When assessing the maturity level of a hospital's integration capabilities using standards like FHIR (Fast Healthcare Interoperability Resources), Antilope, or Euro-CAS (European Clinical Application Suite), there are several artifacts or indicators that can be considered at different levels of maturity. Here's how you might evaluate each:

Maturity levels defined by Hospital on FHIR:

- Basic level: At this level, the hospital might have basic FHIR capabilities implemented, such as being able to retrieve patient demographics or access basic clinical data.
- Intermediate level: The hospital could demonstrate more advanced FHIR capabilities, such as supporting additional FHIR resources like observations, medications, and diagnostic reports.
- Advanced level: At this level, the hospital could demonstrate seamless interoperability with other systems using FHIR, including bidirectional data exchange and support for more complex FHIR resources like care plans, allergies, and immunizations.

Artifacts indicating maturity might include:

- FHIR Server implementation and capability to serve FHIR resources.
- Adoption of FHIR profiles and extensions to represent institution-specific data models.
- Use of SMART on FHIR for integrating third-party applications.
- Implementation of FHIR subscription and event notification mechanisms.

Antilope (Adopting New Technologies in the Lifecycle of Electronic Health Records) was a Thematic Network of core European National organisations supporting the adoption and testing of existing eHealth standards and specifications ad defining an eHealth interoperability framework. Based on the results and recommendations in the Hitch project the network has been set up to promote and drive adoption of testing guidelines as well as testing tools on a European and national level.

It has defined the following maturity levels:

- Basic level: At this stage, the hospital may have started evaluating Antilope concepts and assessing its applicability to their electronic health record (EHR) system.
- Intermediate level: The hospital might have initiated pilot projects or small-scale implementations of Antilope principles within their EHR environment.
- Advanced level: Hospitals at this stage would have fully integrated Antilope standards into their EHR systems, demonstrating comprehensive interoperability and lifecycle management capabilities.

Artifacts might include:

- Documentation of Antilope-compliant data models and data element definitions.
- Implementation of Antilope-conformant workflows for EHR lifecycle management.
- Integration with external systems using Antilope-based messaging and data exchange.

Euro-CAS (European Clinical Application Suite) has been created to develop the sustainable Conformity Assessment Scheme for Europe (CASforEU) and to promote the adoption and take-up of interoperability testing of eHealth solutions against identified eHealth standards and profiles defined in the Refined eHealth European Interoperability Framework (ReEIF).

It has defined the following maturity levels:

- Basic level: Hospitals might have evaluated Euro-CAS and started aligning their clinical applications with Euro-CAS standards.
- Intermediate level: The hospital could have begun implementing Euro-CAS-compliant modules or functionalities within their clinical systems.
- Advanced level: Hospitals fully embracing Euro-CAS would have extensive integration across various clinical applications and demonstrate seamless interoperability following Euro-CAS guidelines.

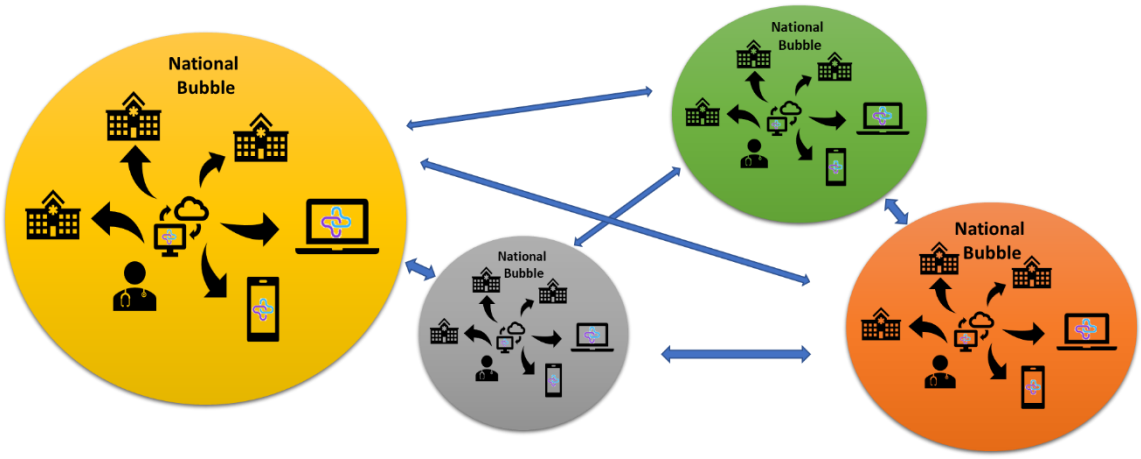
Artifacts indicating maturity might include:

- Adoption of Euro-CAS data models and terminology standards for clinical documentation.
- Implementation of Euro-CAS interfaces and communication protocols for interoperability.
- Integration of Euro-CAS-compliant decision support systems and clinical decision-making tools.
- Assessing maturity levels using these standards involves evaluating not only the technical capabilities but also the extent of adoption and integration within the hospital's overall IT ecosystem and clinical workflows.
- CCMM (Continuity of Care Maturity Model) and EMRAM (Electronic Medical Record Adoption Model) are both frameworks developed by HIMSS (Healthcare Information and Management Systems Society) to assess and guide healthcare organizations in their adoption and implementation of health information technology (HIT) and electronic health records (EHRs). While they serve different purposes, they are both aimed at improving the quality and efficiency of patient care through the use of technology.
- The "circle of trust" paradigm promoted by epSOS (European Patients Smart Open Services), eHDSI (European Health Data Space Initiative) and myHealth@EU refers to a concept in healthcare interoperability and data sharing within the European Union. This paradigm emphasizes the

establishment of trusted relationships among various stakeholders involved in exchanging health data across borders and different healthcare systems.

3 "Circle of trust" paradigm

The figure below shows the vision of the X-Bundle. If this approach is successful, it is necessary to extend it to all stakeholders in the health data space. If we want to implement this as a general practice, then the method tested in epSOS should be used. This means the circle of trust model instead of the current digital handshake.



1. Figure: XpanDH landscape and project vision

Here's how the "circle of trust" paradigm generally works and its key aspects:

- Interoperability Framework: The circle of trust operates within a broader interoperability framework, which sets standards and guidelines for the secure exchange of health data among different healthcare organizations, systems, and countries.
- Trusted Relationships: At the core of the circle of trust are trusted relationships established among participating entities, including healthcare providers, patients, healthcare authorities, and other relevant stakeholders.
- Data Governance and Security: The paradigm emphasizes robust data governance and security measures to ensure the confidentiality, integrity, and privacy of health data throughout its lifecycle. This includes adherence to regulations such as the General Data Protection Regulation (GDPR) in the European Union.
- Consent and Authorization: Patients play a central role in the circle of trust by granting consent and authorization for the sharing of their health data across different healthcare settings and jurisdictions. Transparency and patient empowerment are key principles in this regard.
- Technical Standards and Infrastructure: The circle of trust relies on standardized technical protocols and infrastructure to enable seamless

interoperability and data exchange. This may include the use of common data models, terminologies, and communication protocols such as HL7 FHIR (Fast Healthcare Interoperability Resources).

- Cross-Border Data Exchange: One of the main objectives of the circle of trust is to facilitate cross-border exchange of health data within the European Union, enabling continuity of care for patients who seek treatment or healthcare services in different member states.
- Compliance and Accountability: Participating entities are expected to comply with relevant legal and regulatory requirements, as well as adhere to established best practices and guidelines for data sharing and interoperability. Accountability mechanisms ensure that data handling practices are transparent and accountable.
- Promoting the acceleration of implementation:
- Overall, the circle of trust paradigm represents a collaborative approach to healthcare interoperability and data sharing, with a focus on building trust, ensuring data privacy and security, and promoting seamless exchange of health information to support patient care and public health initiatives across borders within the European Union.

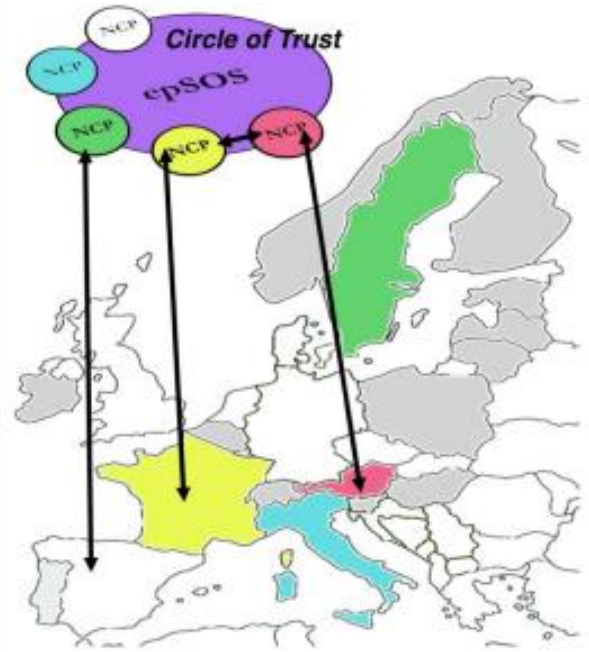


Figure 1: epSOS "overall" picture

A circle of trust is build between NCP in the "epSOS abstract space", the only way a MS can exchange with another MS.

3.1 Guarantee compliance with the "circle of trust" paradigm

Methods and tools for sharing for data practices in the implementation of construction of national and European health data spaces need to be simple and user-friendly, and they must guarantee the privacy of citizens, as well as data security. This is facilitated by the NIS2 Directive, which provides for measures to ensure a high common level of cybersecurity across the EU and which each Member State is obliged to implement in its own legal order. This NIS2 Directive is the EU-wide legislation on cybersecurity. It provides for legal and security measures to increase the overall level of cyber security in the EU.

The EU cybersecurity rules introduced in 2016 were updated by the NIS2 Directive that came into force in 2023. It modernised the existing legal framework to keep up with increased digitisation and an evolving cybersecurity threat landscape. By expanding the scope of the cybersecurity rules to new sectors and entities, it further improves the resilience and incident response capacities of public and private entities, competent authorities and the EU as a whole.

The Directive on measures for a ***high common level of cybersecurity*** across the Union (the NIS2 Directive) provides legal measures to boost the overall level of cybersecurity in the EU by ensuring:

- Member States' preparedness, by requiring them to be appropriately prepared against cybersecurity threats, for example, with a Computer Security Incident Response Team (CSIRT) and a competent national network and information systems (NIS) authority,
- cooperation among all the Member States, by setting up a Cooperation Group to support and facilitate strategic cooperation and the exchange of information among Member States.
- a culture of security across sectors that are vital for our economy and society and that rely heavily on ICTs, such as energy, transport, water supply, financial market infrastructures and healthcare.

Businesses identified by the Member States as operators of essential services in the above sectors will have to take appropriate security measures and notify relevant national authorities of serious incidents. Key digital service providers, such as search engines, cloud computing services and online marketplaces, will have to comply with the security and notification requirements under the Directive.

3.2 Acceptance levels for X-Bubbles have to be at the "high" confidence level according to NIS2

As defined in the *D3.1 – (D3.1.1)-First version of the X-Bundle Readiness model* XpanDH Acceptance Areas document, X-Bubbles are collections of organizations

that have committed to experiment with the use of EEHRxF within a defined acceptance area and under the conditions defined by the X-Bundle. The use cases in the X-Bubbles can be implemented if the resulting exchange of data between partners makes each X-Bubble responsible for adopting and demonstrating the use of digital solutions in a given adoption area and meets the NIS audit expectations assurance level '**high**'.

This aspect is particularly critical, as the functional expectation is relatively simple, but highly dependent on the level of readiness of each organisation, both from a technical and organisational point of view.

The experimentation scenarios envisaged in the X-bubbles of the XpanDH project are illustrated in Figure 1: XpanDH X-bubbles with six bubbles related to six adoption areas considered relevant for the broad adoption of the EEHRxF, taking into account the available resources and experimentation capacity. At this stage, the bubbles involve four countries: Hungary, Portugal, Greece and Slovakia.

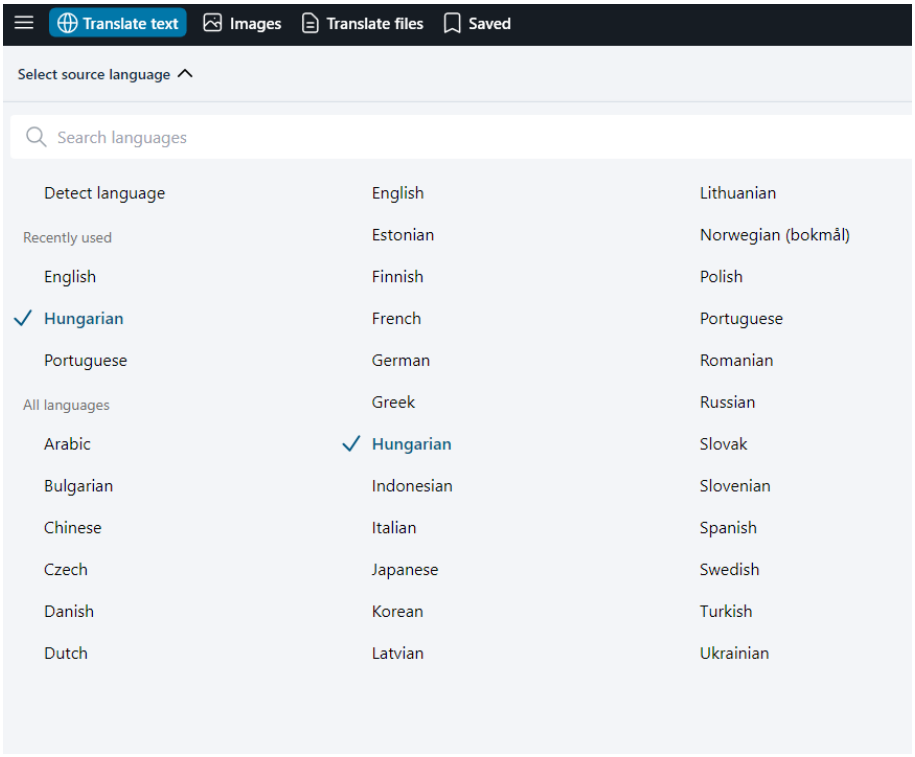
3.3 User-centric approach and multilingualism

Considerations regarding the technical support of standards are not a simple matter, as several conflicting expectations have to be met at the same time. The technological interoperability of the standards analysed is assumed to be based on the availability of the technical documentation necessary for their implementation and their wide acceptance within specific domains. A very good reference for this is the practice already established within countries, with significant evidence from the semantic and syntactic communication standards interface in this report and their work on communication between HealthData@EU nodes. It needs to be decided whether the content of the data access application or data request contains low-level (i.e. accurate information), so that a standard for cataloguing the data source at the metadata or data dictionary level is needed. Once a decision has been made, the conclusions on communication standards in the report may require some adjustment. It is also worth noting that the architecture of HealthData@EU is still under discussion. It is not known whether the final architecture may influence the conclusions and recommendations of this report. However, the sharing of structured and highly encoded data is manageable because it is relatively easy to translate it into another language. However, documents containing free-text descriptions automatic translation can only be performed using AI tools (DL, LLM) which may only serve informal purposes, not the basis of (emergency) medical care. However, it may be highly valuable for patients not speaking the language of the document. E-health technologies can enable patients to access health information, schedule appointments, receive telemedicine consultations, monitor their health through wearable devices, access electronic health records, and participate in online support communities.

Patients need to play an active role in managing their own health and wellbeing and use technology to empower them and enable them to participate more fully in their healthcare. For patients, the EEHRxF aims to improve the interoperability and exchange of electronic health records, which will ultimately benefit patients in terms of better coordination of care, increased patient safety, greater patient empowerment and streamlined access to healthcare services, both within their own country and across European borders.

However, this is only true if patients are able to make choices about the sharing of their patient data. It would therefore be very important that cross-border access to data is part of the right to self-determination in health data. This should also be made possible through mobile apps or by granting permission through a proxy.

If, for example, data stored in the Hungarian EESZT (National eHealth Infrastructure) is downloaded in pdf format, the integrity of the data can be greatly improved if it is electronically signed and time stamped. When downloading, it could also be possible to translate it to a wide variety of languages.



2. Figure Different languages are available in one of the best-known language translators and apps

4 Content analysis of survey made in deliverable of XpanDH D3.1.

Content analysis and recommendations for the survey prepared based on the document D3.1 – (D3.1.1) Define the X-Bundle Readiness model.

1. Structure and clarity of questions:

The structure of the questionnaire is logical and coherent. The questions are generally clear and easy to follow. The new survey structure has significantly improved the ease of completion. During the compilation of deliverable 3.1, there was continuous consultation regarding the content of the questionnaire (XpanDH readiness model questionnaire)

2. Understandability:

Most of the questions are meaningful and understandable. We will provide further feedback on any questions that remain unclear or require further explanation or modification.

3. Mandatory questions:

We believe that making all of questions mandatory is unnecessary. The current approach, where only the initial organizational questions are compulsory, is appropriate.

4. Survey tool usability:

The survey provides a very comprehensive picture of the maturity of the organizations involved in the use case. The current situation in these organizations can be very different due to the development followed previously, so it is sometimes difficult to compare them. In order to be able to handle this, there can be very different answers both in terms of time-related effects and health specialization involvement, so it is important that not a sequential survey is implemented, but one that allows for subsequent modification, as well as internal contradictions with previous answers given in the survey giving answers and thus helping the evaluation. Especially during task 3.3, it will be worth paying special attention to this during the elaboration of the X-Bundle Readiness steppingstone Guides.

The latest version of the survey is much more user-friendly, especially with features like the save-as-draft option. The ability to review and edit previous responses is very useful. These improvements have significantly streamlined the process from starting a survey to submitting it. This enhancement has made the entire process much smoother.

5. Feedback regarding the specific questions:

"3.1 How much does the European Electronic Health Record Exchange Format (EEHRxF) affect your organisational policies and procedures?"

The transformation of existing systems requires due care. Before this question, it would be worthwhile to include a question that asks about the preparation of the implementation plan of different X-Bubbles.

As a matter of policy, this question can be answered if an implementation plan was drawn up, including the additional costs associated with the transition of the format.

"3.24 How much does the European Electronic Health Record Exchange Format (EEHRxF) affect your care processes?"

There is a contradiction here. If a (significant) improvement of care occurred, it indicates that the system has not functioned well so far. EEHRxF is unlikely to have an impact on the side producing the data, only on the side receiving the data. At the national level, such as in Hungarian healthcare, the impact is marginal, because the receiving side already receives human readable medical documents. On the receiving side, its impact should be mostly felt at a pan-European level. The mechanism of impact will change, so this issue needs to be reconsidered.

Changing the health data subsystems will give a new quality if the benefits of the EU-wide adoption are felt and they will affect the origin (initial) subsystems. In order to make the EEHRxF ecosystem acceptable for the stakeholders, we need to know the local maturity, while the local transformation motivations are influenced by the future structure. This question is closely related to the examination of the expected long-term effects and the changing flow, which cannot be derived from the current local maturity models. For this, it will be worthwhile to start from the expected benefits that full structured digitalization with the help of EEHRxF can mean.

"3.28 Have you identified (potential) barriers during implementation of changes to your care processes induced by the EEHRxF?"

These questions can be answered once a feasibility study and an implementation strategy have been conducted. Therefore, open-ended responses are needed here.

"4.1 How much does the European Electronic Health Record Exchange Format (EEHRxF) affect training and acceptance of your healthcare professionals?"

The LRR is typically already has a structured (internal) format with a significant degree of automation and the necessary human evaluation during data validation. HDR currently contains highly structured elements at a minimal level and is typically created by a physician either fully manually or with only limited assistance provided by the HIS, it typically contains a significant number of professional abbreviations, which are typically profession-, country, and sometimes even hospital-specific. Thus, in these cases, a completely different approach is required, so the maturity of this cannot be answered in one question.

The issue of training of and acceptance by your healthcare professionals should be addressed separately and divided into two parts as the LRR is essentially a (sub)system development/integration task, while the creation of HDR without the training of physicians is likely to fail.

"4.9 How much does the European Electronic Health Record Exchange Format (EEHRxF) affect your clinical documentation in terms of information elements and terminologies?"

This is where the EEHRxF should have a deep impact. The question should be divided into short-term and long-term impacts where the human factor is involved, such as HDR, the question should be split. Similar to the opinion given on question 4.1, the significant difference between LRR and HDR applications should be taken into account.

"4.18 In terms of "Terminologies": What is your strategy to align the terminologies to the EEHRxF?"

The issue of transition should be addressed separately and divided into two parts:

1) short-term solution

2) end goal (target solution).

In some cases, the transformation of the data usage of organizations can be very fast, while in other cases can be very slow. The most difficult issue in terminology is the conscious change of usage terminology and usage practice developed in the human workforce. It can be very effective if the transformation time can be shortened on the experience of the current practices. Current practice shows that LRR: LOINC adaptation will be mapped, technical code systems may be replaced but the strategy hasn't been decided yet.

In the case of HDR, this is a much more difficult to realize in many cases. It would be nice if we could offer examples of potential strategies to follow, thereby saving most of the stakeholders from having to invent and adapt an individual strategy.

"4.22 Do/did you need to implement or update a terminology to accomplish the alignment to the EEHRxF terminologies?"

For clarity, the word "Service" should be included in the question. It should read:

"Do/did you need to implement or update a Terminology Service to accomplish the alignment with the EEHRxF terminologies?"

"5.1 How much does the European Electronic Health Record Exchange Format (EEHRxF) affect your IT Infrastructure?"

As previously suggested in several questions, the two areas (LRR, HDR) should be treated separately, as LRR is well-structured and automated, whereas HDR is handled manually. Therefore, this question should be split into two parts.

"5.6 Have you identified (potential) challenges and risks in regards of the implementation of EEHRxF enabled applications?"

In the case of individual providers or systems, the risk in the case of LRR and HDR and the opportunities inherent in EEHRxF can be completely different, therefore the challenges and risks should be separated, as it is not ideal to treat them together; one provides utility while the other increases exposure.

Among the options, it would be worthwhile to specify the middle option as well, since in theoretically it can also be indifferent. The answer "Yes (Medium challenges/risks)" is missing.

"5.16 Are you aware of Interoperability Testing possibilities for the European Electronic Health Record Exchange Format (EEHRxF)?"

This question as it is currently is confusing. We questioned the definition of terminology and how it should relate to the previous documentation regime. This needs to be clarified.

„Not checked for it yet" - there is no sense in explaining the answer to 5.17.

"5.18 Have you decided on an Interoperability Testing framework and processes?"

In order to transform the existing systems, it is necessary that both data owners and data managers make the necessary decision to introduce the transition to the EEHRxF format, therefore the following answer is missing for this question:

„No, we haven't decided yet if we need an Interoperability Testing framework and processes"

"6.3 Have you identified (potential) improvements on patient outcomes through the deployment of EEHRxF?"

It is conceivable that EEHRxF may be indifferent to patients, hence the answer: "Yes (medium improvements)" is missing.

"6.7 Anything else you want to let us know?"

When commenting on the survey, we were only able to note on this point that "It would be useful if the survey included an assessment of the cost-benefit approach differentiated according to the groups of interested parties."

The 3.1 questionnaire we know does not examine the budgetary benefits of implementing EEHRxF. This question cannot be avoided, because every transformation has costs and without planning the costs necessary for the transformation, the transformation will not happen. From the point of view of the project, this is an expectation of the partners, however, from the partners' side, it is a task to be implemented, which greatly affects the maturity level.

The X-Bubbles are collections of organisations that agreed to experiment with using the EEHRxF, in a set adoption domain and under the X-Bundle defined conditions, mostly on their own budget, or using other projects budgets, or pro-bono, but in effective articulation with XpanDH. Each X-Bubble is responsible for adopting and demonstrating the use of digital solutions for a specific adoption domain.

5 Conformance assessment of X-Bubbles

The contributions of X-bubbles to XpanDH are described in the D4.1 – (D4.1.1) XpanDH Adoption. In terms of compliance assessment, significant differences can be observed between the different Bubbles.

X-Bubble 1

This X-Bubble focuses on piloting structured data exchange system to enhance the continuity of care for diabetic patients.

X-Bubble 2

The main objectives in terms of health information exchanging are:
• to deliver comprehensive information to patients,
• to handle lab results information adopting EEHRxF.

X-Bubble 3

The main objectives in terms of health information exchanging are:
• to deliver comprehensive information to patients,
• to handle discharge report information adopting EEHRxF.

X-Bubble 4

The main objective, in terms of health information exchange, is to pilot the use of the National Discharge Report/Letter Format which will incorporate EEHRxF specifications:

- to contribute to the collection of structured and coded information on patient administrative data (as defined in the Greek DRG-Dataset),
- to contribute to the collection of relevant clinical data, using ICD-10 Greek Modification, and GMPC/ETIP (as foreseen in Greek DRG Coding Guidelines),
- to achieve fair Remuneration for given Hospital Services by EOPYY and other insurance organizations.

X-Bubble 5

The main objective, in terms of health information exchange, is to pilot the use of DRG data, contained in a National Discharge Report/Letter Format which will incorporate EEHRxF specifications in a structured and coded format (selection of data to be determined):

- to contribute to the validation and cross-check of structured and coded information on patient administrative data (as defined in the Greek DRG-Dataset),
- to contribute to the validation and cross-check of relevant clinical data, using ICD-10 Greek Modification, and GMPC/ETIP (as foreseen in Greek DRG Coding Guidelines),
- to transmit DRG codes and names for each patient, computed by the algorithm of the Greek DRG Grouper Platform, according to the above validated and cross-checked patient data.

Additional objectives may include:

- to provide Discharge data in the case of care transition (patient transfer etc.) to ensure continuity of care,
- to provide Discharge data to support Patient Access.

X-Bubble 6

The main objectives are:

- Improve Cross-border Collaboration: The successful implementation of the cross-border exchange of hospital discharge reports contributes to the overall objective of enhancing collaboration between healthcare systems in different countries. It facilitates the seamless transfer of critical patient information, enabling better continuity of care for individuals seeking healthcare services across borders.
- Enhance Semantic Interoperability: By utilizing international standards like FHIR, the X-Bubble aims to enhance semantic interoperability between the national information systems of Slovakia and Hungary. It promotes the use of common coding systems and predefined value sets, which facilitates the accurate interpretation and exchange of health data, leading to improved data quality and information sharing.
- Support Data-driven Healthcare: The exchange of hospital discharge reports enables the availability of comprehensive and up-to-date health information, supporting data-driven healthcare practices. It contributes to the overall objective of the XpanDH project by enhancing the collection, aggregation,

and analysis of health data, which can lead to better insights, research, and decision-making for healthcare providers and policymakers.

- Foster Standardization Efforts: The X-Bubble's use of international standards and the demonstration of successful exchange contributes to standardization efforts within the healthcare domain. It showcases the feasibility of interoperability between different national information systems and encourages the adoption of standardized formats and coding systems for the exchange of health data.

Conclusion from the X-Bubbles

In conclusion, the Laboratory Results Report (LRR) and Hospital Discharge Report (HDR) use cases may seem to require separate treatment:

Laboratory Results Report (LRR):

- The LRR handles data that are already available – in at least the Laboratory Information System (LIS) – in a structured format. Therefore, the particular X-bubble needs to demonstrate that:
  - the LRR created by the producer is equivalent to the currently created one,
  - the LRR displayed to the user of the receiving system (whether a physician or a patient) is equivalent to the source document.
- The LRR could be treated as an addition to the original report, and both could be sent to the receiver.

Hospital Discharge Report (HDR):

- The HDR use case introduces a new structured document, where the creation of such a document is a great challenge. The transformation of the already existing semi-structured documents handled by the hospital information systems seems to be unfeasible. Instead, the discharge report should already be created in a structure semantically compliant with EEHRxF. This new approach will only be accepted by physicians if it is automated as much as possible.